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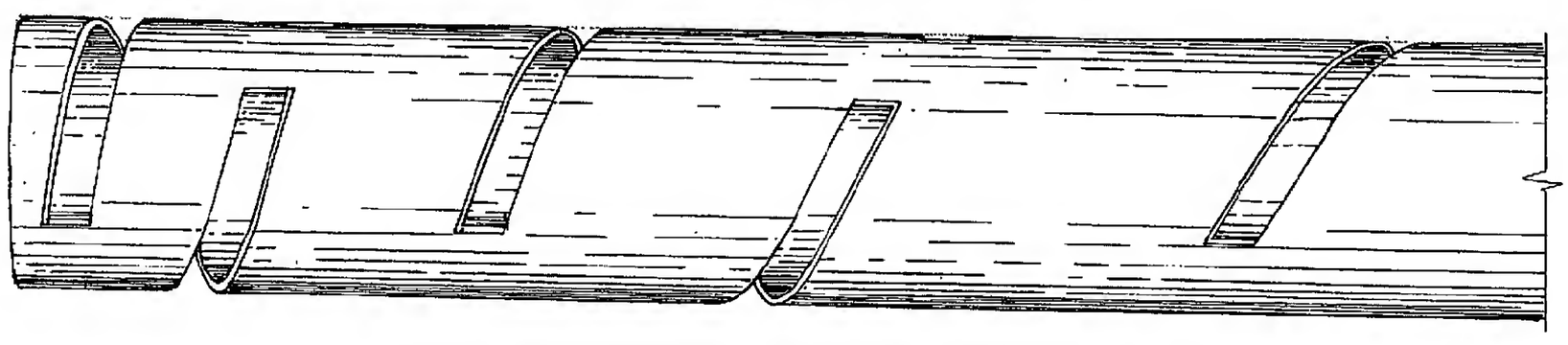
(54) Title: PIPE HAVING AT LEAST A PORTION WITH A VARIABLE FLEXIBILITY



(57) Abstract: Tube, in particular for the use in medical devices in the form of catheters for endoluminal operations, wherein in at least one portion of its wall there are obtained notches (either slits or grooves) such as to locally increase the flexibility of the tube. The notches are provided in at least one distal zone of said tube.

DESCRIPTION

"PIPE HAVING AT LEAST A PORTION WITH A VARIABLE FLEXIBILITY"

[0001] The present finding relates to a tube for the use in medical devices in the form of catheters, especially but not particularly used in angioplasty operations.

[0002] The use of a metal tube for medical devices of the type considered herein is known. Since these devices must be capable of being introduced into a body through natural ducts up to the part to be treated, the tube used therein, at least in its forward or distal portion, must exhibit suitable flexibility to follow even the turns of these ducts without damaging them.

[0003] Systems for flexibilising a stiff metal tube have already been proposed but they have been found capable of being improved anyway.

[0004] The present finding therefore aims at proposing a metal tube obtained by an innovative method for flexibilising it which is simple, easy and inexpensive to be realised.

[0005] Correspondingly, the object is that of providing a tube configured in at least portion of its length to be more flexible than in the remaining portion of tube, particularly with a variable flexibility along the same portion, to facilitate its use in the aforementioned medical devices.

[0006] Another object of the invention is that of obtaining that the variation of flexibility is such as to allow a gradual passage between the non-flexibilised portion of tube and the front portion or distal end so that the latter is very flexible.

[0007] A further object of the present invention is that of obtaining a tube having constant flexibility in any radial direction.

[0008] Such object is obtained by a tube according to claim 1.

[0009] Such object and further purposes are achieved by a metal tube characterised in that in at least one portion of its wall there are obtained notches so as to increase the local flexion of the tube. According to the needs, the notches in the tube wall substantially exhibit a discontinuous helix shape pattern.

[0010] Further features of the finding will appear more clearly from the following description made with reference to the attached indicative and non-limiting drawings, wherein:

[0011] Fig. 1 shows a three-dimensional view of a piece of tube with a flexibilised portion according to an embodiment;

[0012] Fig. 2 shows an enlarged portion of the tube of Fig. 1;

[0013] Fig. 3 shows a schematic plane view of the tube of Fig. 1;

[0014] Fig. 4 shows an enlarged portion of Fig. 3;

[0015] Fig. 5 shows a transversal section in the direction of arrows A A on Fig. 3;

[0016] Figs. 6 and show two more transversal sections respectively according to arrows B B and N N on Fig. 4;

[0017] Fig. 8 shows the plane development of the cylindrical surface of the tube of figure 1;

[0018] Fig. 9 shows the plane development of the cylindrical surface of the tube according to another embodiment;

[0019] Fig. 10 shows the plane development of the cylindrical surface of the tube according to a further embodiment;

[0020] Fig. 11 shows the plane development of the cylindrical surface of the

tube according to a further embodiment;

[0021] Fig. 12 shows a perspective view of the tube of figure 9;

[0022] Fig. 13 shows a perspective view of the tube of figure 10;

[0023] Fig. 14 shows a perspective view of the tube of figure 11;

[0024] Fig. 15 shows some different possible geometries of the notches.

[0025] The tube proposed herein exhibits a wall 11 and, in a distal area 12, at least one portion 13 of its length which is flexibilised compared to the tube's own stiffness.

[0026] According to an embodiment, the flexibilised portion 13 extends for a length comprised between 70mm and 110mm, preferably between 80mm and 100mm, measured starting from the distal end.

[0027] For its flexibilisation, in the wall of such portion 13 of the starting tube there are obtained notches 14. The term "notch" means both a thorough slit that at least in one portion passes through the entire thickness of the tube wall, and a groove that in no portion passes through the entire thickness of the tube wall.

[0028] Such notches 14 are spaced out by full portions and exhibit, for example, a substantially discontinuous helical pattern. This helical pattern of notches 14 can be with one or more starts.

[0029] If an even flexibility is required along the entire flexibilised portion 13, notches 14 for example are all the same by size and depth, and step P of their helical pattern is constant (Fig. 8).

[0030] However, to better satisfy the convenience of use and the performance of the tube used in a catheter, the flexibility of the flexibilised portion 13 preferably is variable, to be higher in the vicinity of the distal end

and decrease in the opposed direction.

[0031] According to an embodiment, a notch exhibits, at least for some portions of it, prevailing longitudinal extension that determines a notch direction.

[0032] The flexibility of portion 13 can therefore be selected and realised in various manners. For example, it is possible to vary the inclination angle α of notches 14 between said notch direction and a circumference obtained on the outside surface of the tube and/or increase step P.

[0033] Or, it is possible to vary the depth of notches 14, for example the arc of removal of material from the tube wall 11, reducing it away from the distal end.

[0034] Similarly, the flexibility along the flexibilised portion 13 can be diversified by varying the width A of notches 14, also in this case by reducing it starting from the zone close to the distal end. The width A of the notches cam be varied starting from a minimum (Fig. 15a) which is equal, for example, to the useful width of the cutting tool. According to a preferred embodiment, the minimum notch width is the typical width of a cut obtained by laser technology. Such minimum width therefore is comprised between about 5μm and about 30 μm, preferably between about 10 μm and about 25 μm.

[0035] A larger width A can be obtained by a rectangular notch as that shown in figure 15b or with a parallelogram notch. A similar notch imparts higher deformability (both flectional and axial) to the tube and reduces the over-tension or stress concentration effect that typically generates around the apices of a notch. The width of such notch can be as much as about 1

mm.

[0036] It is also possible, in order to reduce the stress concentration effect around the notch apex without having to increase the tube deformability, to use a cut geometry as that shown in figure 15c, wherein the width A of the notch is determined on the basis of the need of flexibilising the tube, whereas the notch apices' over-tensions are relieved by circular holes whose diameter D is larger than the width A of the notch.

[0037] According to a further embodiment, the flexibility along the flexibilised portion 13 can be diversified by thinning out notches 14 starting from the zone close to the distal end. As an alternative, a variable flexibility at the flexibilised portion 13 can be obtained by applying a combination of two or more of the above systems, with reference to the shape, to the arrangement and pattern of notches 14 in the tube wall.

[0038] Reference shall be made below to the figures from 8 to 11, which show the plane developments of the cylindrical outside surfaces of the flexibilised portions 13 of the tube according to some embodiments.

[0039] Figure 8 shows the plane development of the outside tube surface according to an embodiment. According to such embodiment, notches 14 are arranged with a constant inclination. The notches, for example, exhibit a width of about 90° and a reciprocal phase displacement of about 120°. The notch width is the measure of the arc that separates, on a circumference on the tube outside surface, the projection of the notch start from the projection of the notch end. The notch start and end are respectively defined as the distal end and the proximal end of the notch. The phase displacement F between the notches is the measure of the arc that on the same

circumference separates the projection of the start of a first notch from the projection of the start of a second notch. If with E and phase displacement F are defined, it is also possible to define an angular distance G equal to the difference between phase displacement F and width E.

[0040] Figure 9 shows the plane development of the outside tube surface according to another embodiment. According to such embodiment, notches 14 are arranged with null inclination α. In other words, the notches are perpendicular to the tube axis. The notches, for example, exhibit a width E of about 240° and a phase displacement F of about 120°. The expert of the art will promptly understand that in this embodiment it is not possible to keep the definition given above of "start" and "end" of the notch, since both ends are located at the same axial distance from the distal end. The expert of the art will also clearly see that in any case it is possible to arbitrarily identify, in each notch, an end as start and the other end as end of the same notch.

[0041] According to a further embodiment, the axial distance between two consecutive notches starts from a value B and increases every time, for example by an amount C. Since proceeding from the distal end in a proximal direction the axial distance between the notches increases continuously, a very gradual passage is obtained in this embodiment from the flexibility of the non-machined tube to the distal end, which is the most flexibilised.

[0042] Figure 10 shows the plane development of the tube outside surface according to à further embodiment. According to such embodiment, notches 14 are arranged with increasing step P and inclination. The inclination starts

from a value α and increases by an amount β at each arc γ covered on an outside circumference in terms of width E of each notch and of angular distance G between two consecutive notches. According to the specific construction requirements, arc γ can take measures comprised between 0° and 360°. In the example shown in figure 10, arc γ measures 360°; in other words, the inclination of the notches is increased by an amount ρ at each full revolution made on the outside surface of the tube in terms of notch width E and angular distance G.

[0043] Starting from the distal end in proximal direction, the notches have an increasing length but their width in degrees measured on an outside circumference of the tube is constant. For example, the notches have a width E of 180° and a phase displacement F of 240°. This particular embodiment allows obtaining, for the deformed tube, a very regular profile whose curvature varies continuously.

[0044] Figure 11 shows the plane development of the outside tube surface according to a further embodiment. According to such embodiment, notches 14 are arranged with increasing step P and inclination. In the example shown, arc γ is of 60°; in other words, the notch inclination which at the beginning is equal to α is increased by an amount β at each arc of 60° covered on the outside surface of the tube in terms of notch width E and angular distance G.

[0045] Starting from the distal end in proximal direction, the notches have an increasing length but their projection in terms of degrees on an outside circumference of the tube is constant. For example, the notches exhibit a width E of 240° and a phase displacement F of 300°. These special values

allow obtaining a very even flexibility as the radial stressing direction varies. Moreover, this particular embodiment allows obtaining, for the deformed tube, a very regular profile whose curvature varies continuously.

[0046] In the embodiments shown in figures 10 and 11 it is possible to define an axial distance between consecutive notches. So is defined the distance that separates the projections of the respective starts of the notches on the axis or on a generatrix of the tube cylindrical surface. Note that also in these embodiments the axial distance between two consecutive notches increases from the distal end of the tube in proximal direction.

[0047] The flexibilised tube according to the invention can be realised with metal materials, preferably with stainless steel, with polymeric materials or with composite materials.

[0048] According to a preferred embodiment, the tube surface is covered with a layer of polytetrafluoroethylene (PTFE), for example Teflon®, produced and marketed by Du Pont.

[0049] The fact that the tube is flexibilised by a plurality of different and separate notches ensures a great residual resistance ot the tube, along with an optimum flexibility.

[0050] Several changes, adaptations and replacement of elements with functional equivalent ones can be made by a man skilled in the art to the preferred embodiments described above without departing from the scope of the following claims.

CLAIMS

1. Tube, in particular for the use in medical devices in the form of catheters for endoluminal operations, wherein in at least one portion (13) of its wall (11) there are obtained notches (14) with width A such as to locally increase the flexibility of the tube, said notches (14) being provided in at least one distal zone of said tube.

2. Tube according to claim 1, comprising a plurality of notches having a predetermined axial distance from one another.

3. Tube according to claim 2, wherein said axial distance between said notches increases from the distal end in proximal direction.

4. Tube according to any one of the previous claims, wherein said notches form an angle α with a circumference obtained on the outside surface of said tube, said angle α having constant width.

5. Tube according to any one of claims from 1 to 3, wherein said notches form an angle α with a circumference obtained on the outside surface of said tube, said angle α having increasing measure from the distal end in proximal direction.

6. Tube according to claim 5, wherein said width of said angle α increases by an amount β at each arc γ covered on the surface of the tube in terms of width E of each notch and of angular distance G between two consecutive notches.

7. Tube according to claim 6, wherein the measure of said arc γ is comprised between 0° and 360°.

8. Tube according to any one of claims from 1 to 3, wherein said notches are arranged perpendicularly to the longitudinal axis of the tube.

9. Tube according to any one of the previous claims, wherein said notches have a width comprised between 5 μm and 1 mm.

10. Tube according to any one of the previous claims, wherein said notches have a width comprised between 10 μm and 25 μm.

11. Tube according to any one of the previous claims, wherein at at least one of the ends, said notches comprise a circular hole having a larger diameter than the notch width.

12. Tube according to any one of the previous claims, wherein the portion comprising said notches extends from the distal end in proximal direction for a length comprised between 70 and 110 mm.

13. Tube according to any one of the previous claims, wherein the portion comprising said notches extends from the distal end in proximal direction for a length comprised between 80 and 100 mm.

14. Tube according to any one of the previous claims, wherein said tube is realised with a metal material.

15. Tube according to any one of the previous claims, wherein said metal material is stainless steel.

16. Tube according to any one of claims from 1 to 13, wherein said tube is made of a composite material.

17. Tube according to any one of claims from 1 to 13, wherein said tube is made of a composite material.

18. Tube according to any one of the previous claims, wherein the surface of said tube is covered with a layer of polytetrafluoroethylene (PTFE).

19. Catheter for endoluminal operations comprising a tube according to any one of the previous claims.

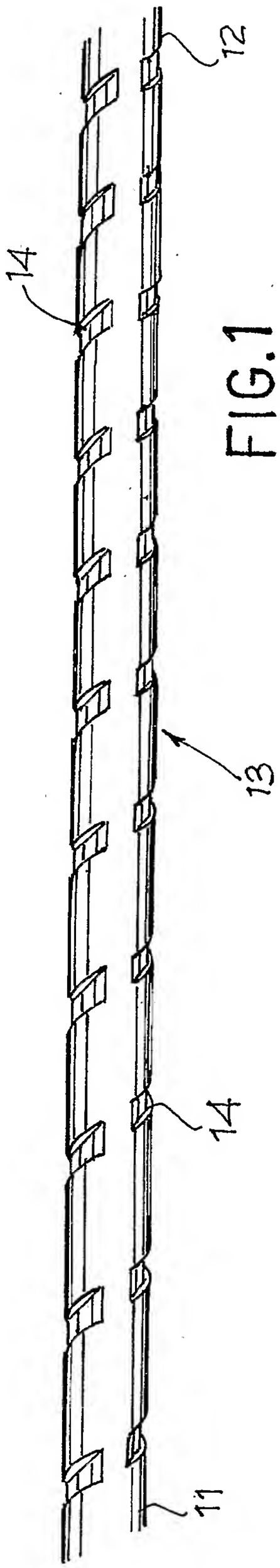


FIG.1

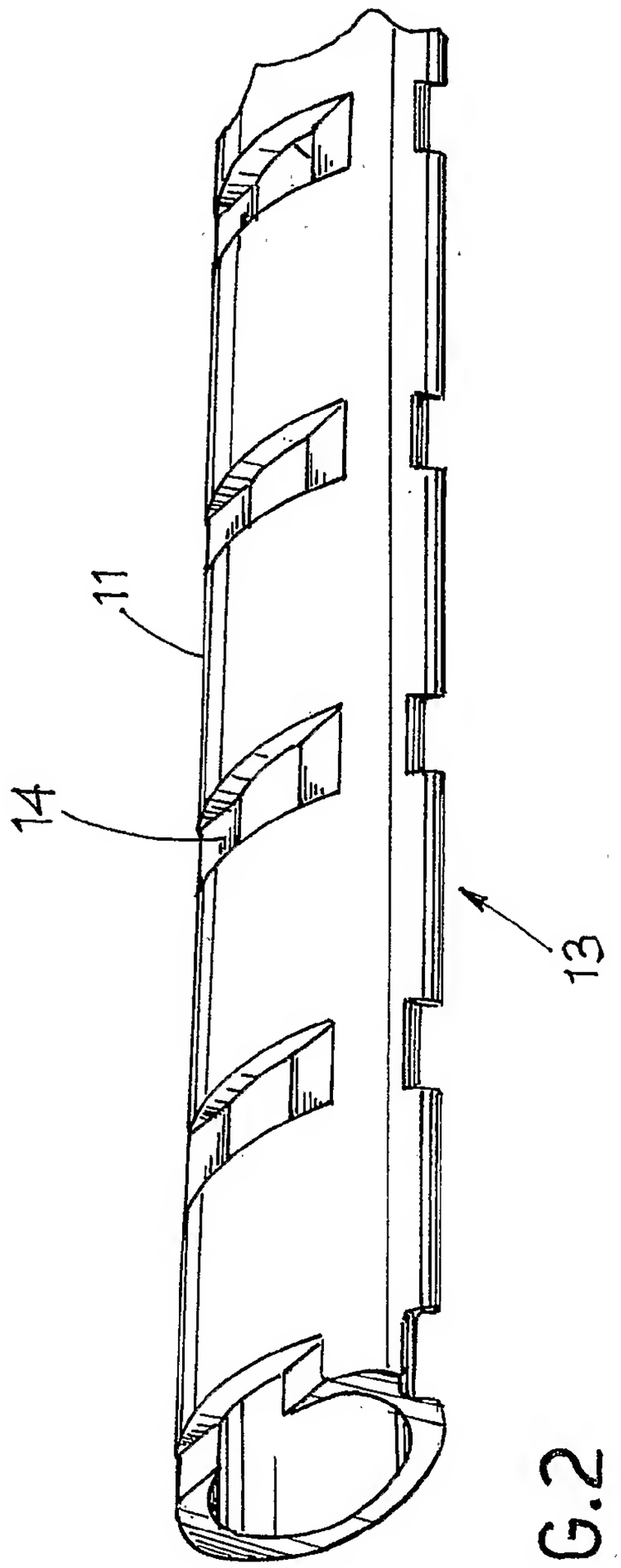


FIG.2

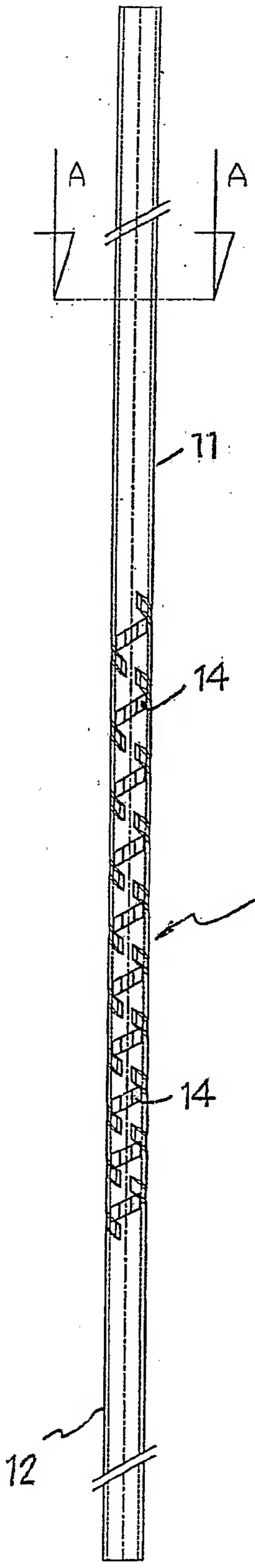


FIG.3

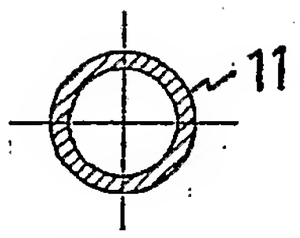


FIG.5

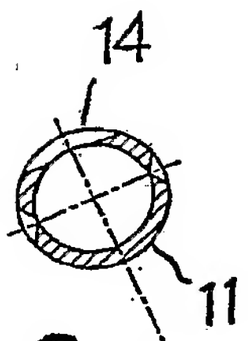


FIG.6

FIG.7

FIG.4

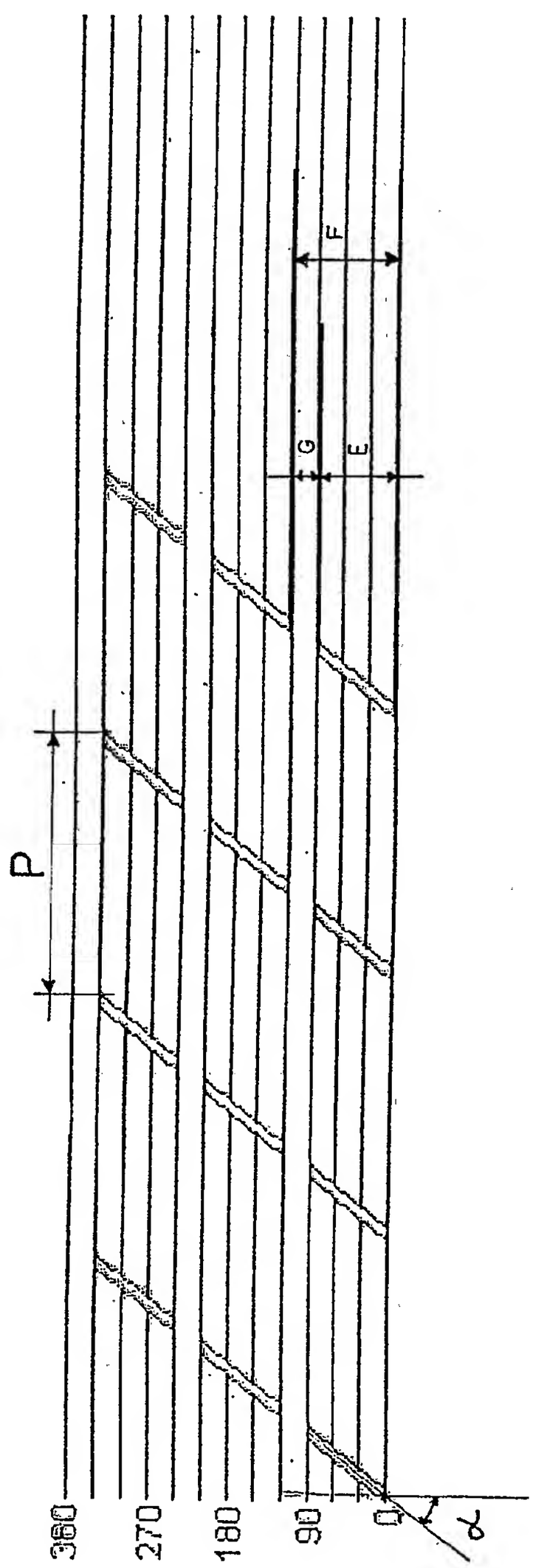


FIG. 8

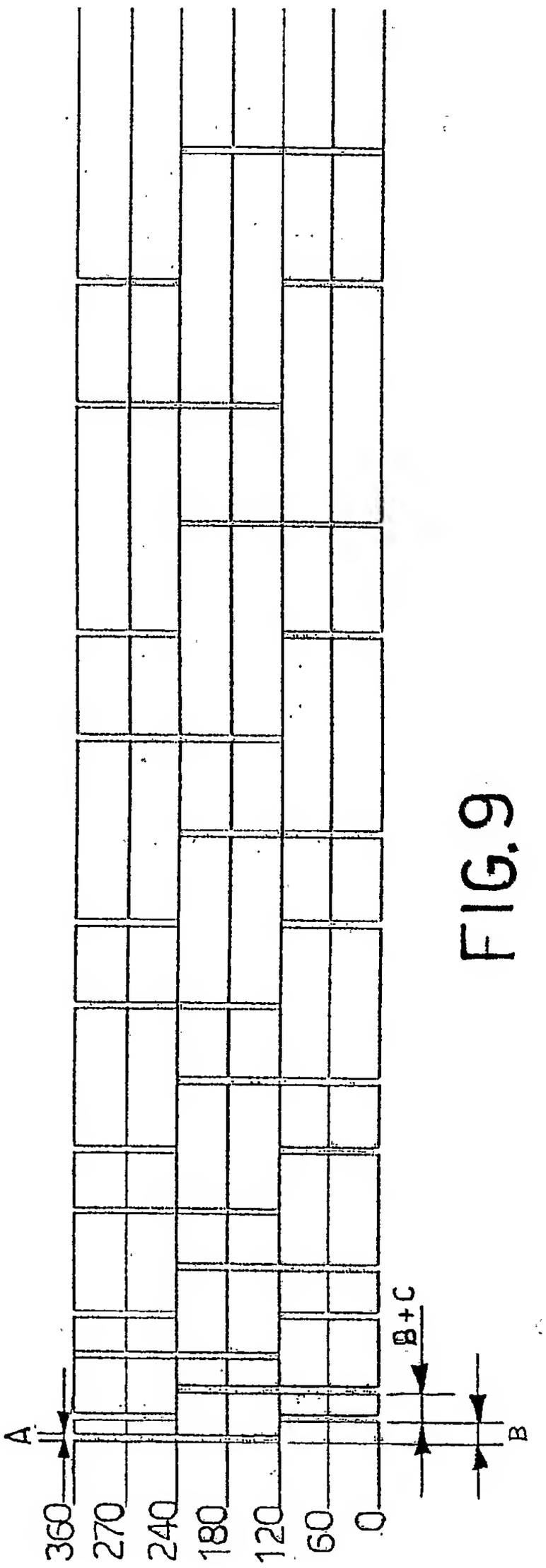


FIG.9

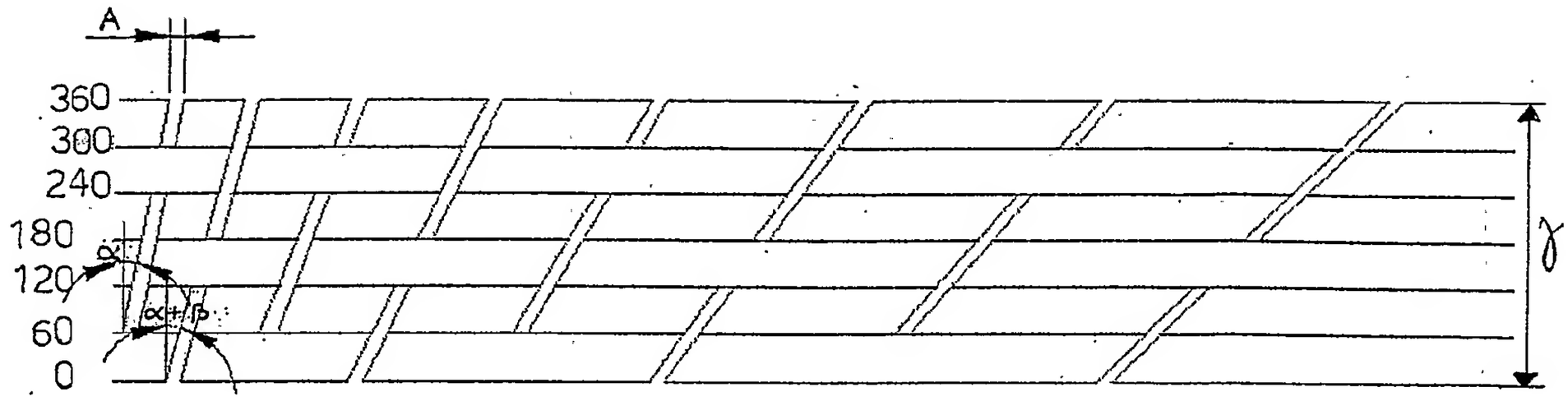


FIG.10

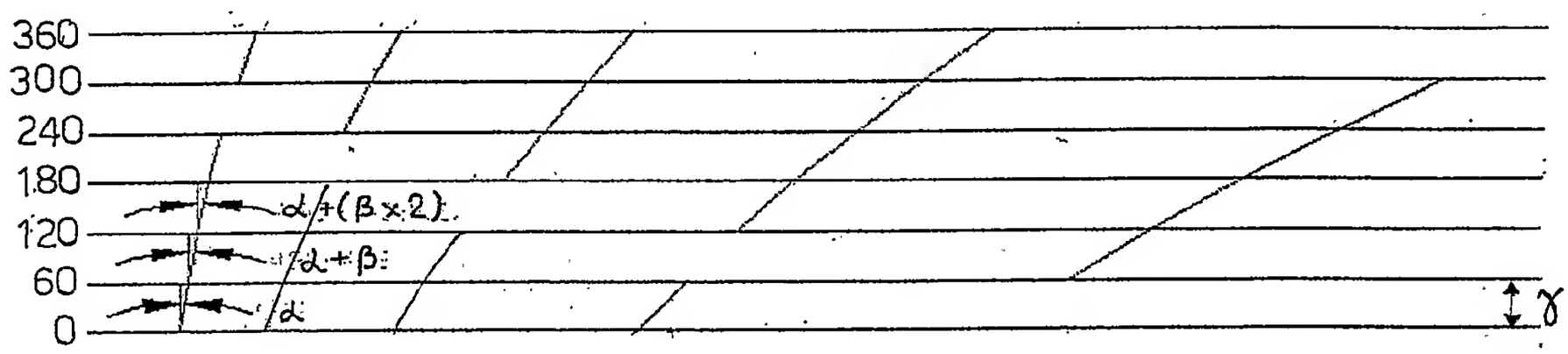


FIG.11

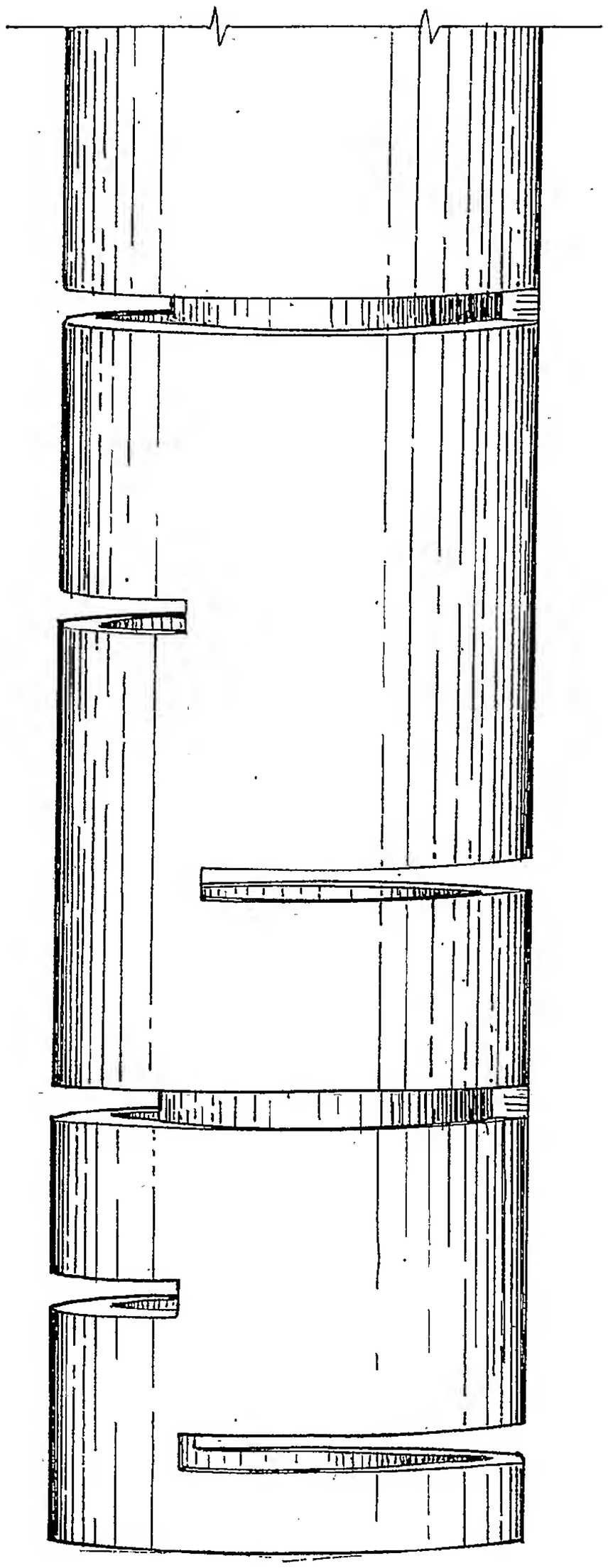


FIG.12

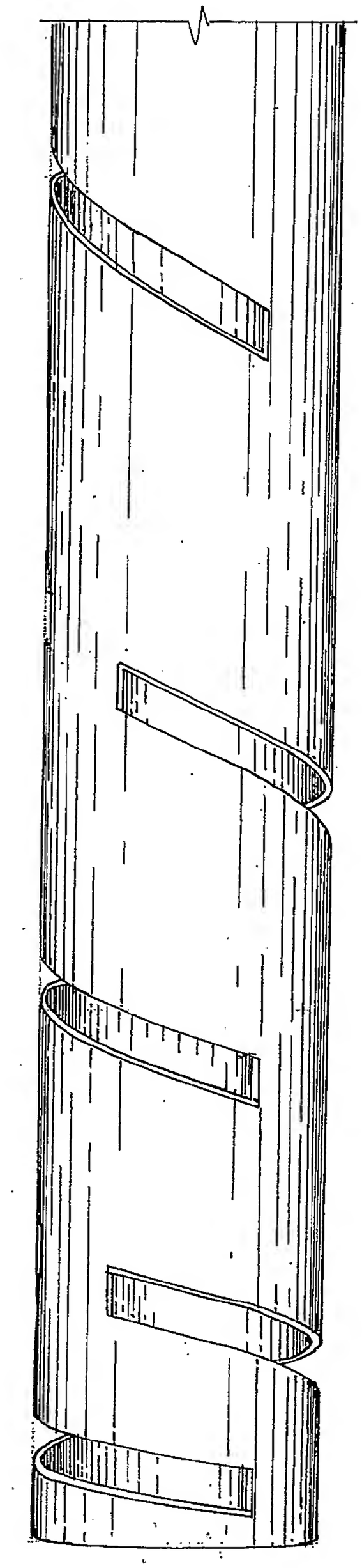


FIG.13

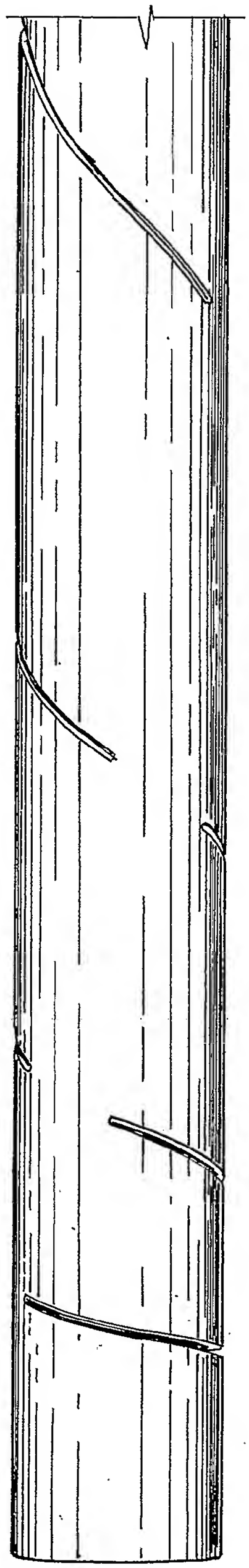


FIG.14

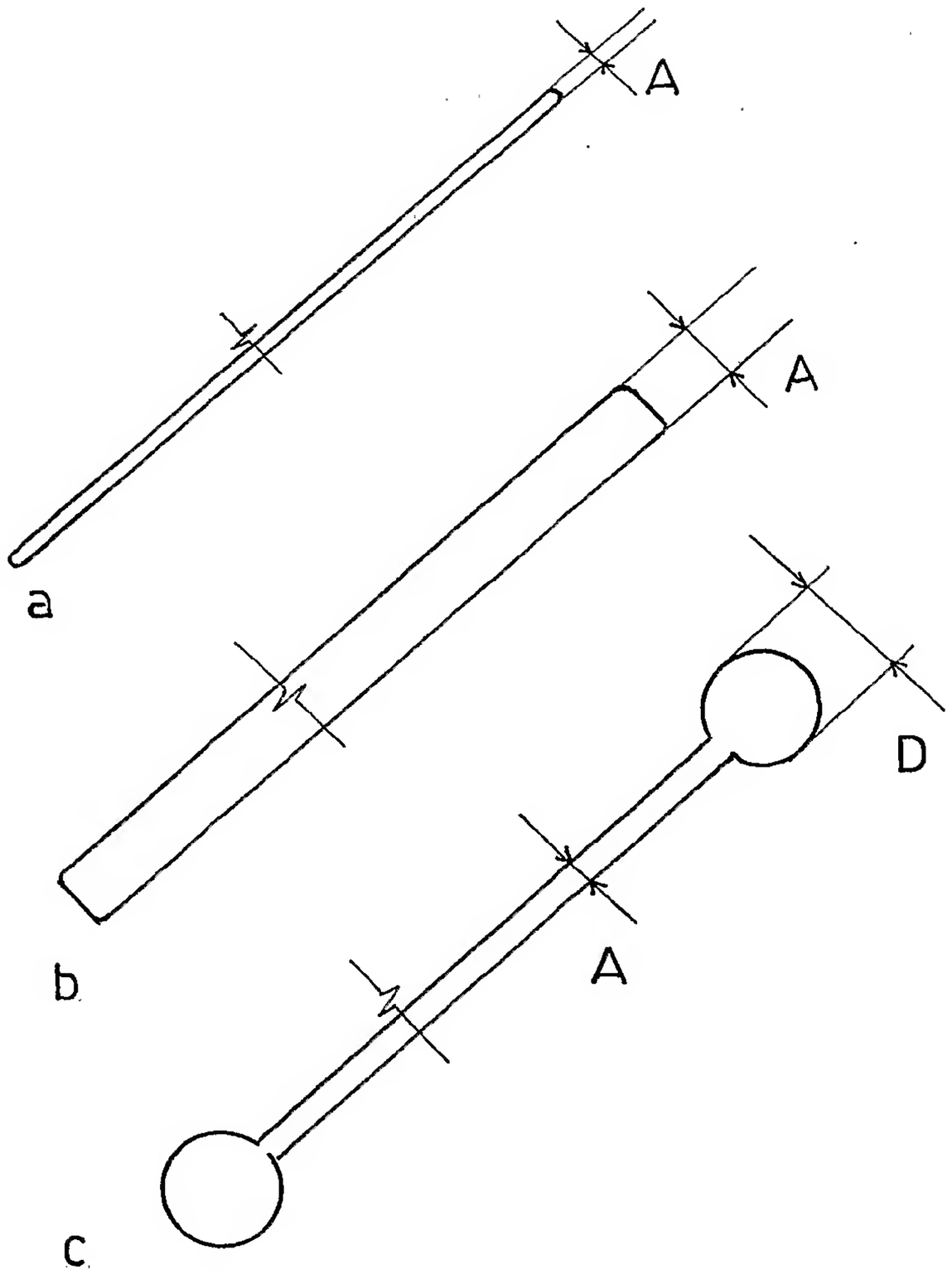


FIG. 15

INTERNATIONAL SEARCH REPORT

Inte nal Application No
PCT/IT 03/00777

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X	EP 0 937 481 A (PRECISION VASCULAR SYSTEMS INC) 25 August 1999 (1999-08-25) figure 3	1-3,19

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
13 April 2004	20/04/2004

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INTERNATIONAL SEARCH REPORT

Intel nal Application No
PCT/IT 03/00777

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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Form PCT/ISA/210 (continuation of second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte[illegible]onal Application No
PCT/IT 03/00777

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